Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 2C on sheet 1, changes to Fig. 5 on sheet 2, changes to Fig. 6 on sheet 3, and changes to Figs. 7 and 8 on sheet 4. In addition, Fig. 9 is newly added on sheet 3.

In Fig. 2C, reference numerals have been added.

In Fig. 5, reference numeral 500 is replaced with the reference numeral 400 and section slice arrows 9-9 are added.

In Fig. 6, reference numeral 500 is replaced with the reference numeral 400 and reference numerals V7 and V8 are added.

In Fig. 7, reference numeral 500 is replaced with the reference numeral 400, reference numerals V7 and V8 are added, and reference numerals 602 and 604 are added.

In Fig. 8, reference numeral 500 is replaced with the reference numeral 400, reference numerals V7 and V8 are added, and reference numerals 602 and 604 are added.

Fig. 9 is a newly added drawing onto Sheet 3.

Attachments: Four Replacement Sheets

REMARKS

Claims 42-48, 52-57, and 60 are pending in the application with claims 42, 60, and 61 being the independent claims. Applicants request reconsideration in view of the following remarks.

This paper does not raise new issues nor requires a new search. Therefore, it should be in condition for immediate action by the Examiner. Accordingly, Applicants respectfully request that the Examiner enter this paper, consider the remarks herein, and allow the application.

Drawings

The Office Action required a new drawing explicitly showing the elastic material disposed through first and second openings as recited in independent claims 42 and 60. By this paper, Applicants add new Fig. 9 showing the cross-sectional view with the elastic material as requested. In addition, Fig. 5 is amended to include section arrows 9-9.

This paper also amends Fig. 2C on sheet 1, Fig. 5 on sheet 2, Fig. 6 on sheet 3, and Figs. 7 and 8 on sheet 4. More particularly,

in Fig. 2C, reference numerals have been added;

in Fig. 5, reference numeral 500 is replaced with the reference numeral 400 and the section view arrow 9-9 is added as mentioned above;

in Fig. 6, reference numeral 500 is replaced with the reference numeral 400 and reference numerals V7 and V8 are added;

in Fig. 7, reference numeral 500 is replaced with the reference numeral 400, reference numerals V7 and V8 are added, and reference numerals 602 and 604 are added; and

in Fig. 8, reference numeral 500 is replaced with the reference numeral 400, reference numerals V7 and V8 are added, and reference numerals 602 and 604 are added.

No new matter is added by these changes.

The changes bring the drawings into conformance with the specification.

Amendments to the Specification

This paper amends the specification to properly identify the new drawing Fig. 9.

Compliance with 35 U.S.C. §112

The Office Action rejected claims 42-48, 52-57, 60, and 61 under the second paragraph of Section 112 indicating that the it is "unclear if applicant is claiming the individual parts which must be flexible relative to the vertebrae, or if applicant is trying to claim that the entire device, shown in Fig. 4, is itself a 'flexible member.'" Office Action, p.3-4.

The Office Action indicates that the use of both "flexible member" and the use of "joint component" is confusing and that in at least one interpretation, would seem to require at least four elongated portions or legs.

For clarification, Applicants provide one exemplary claim interpretation below. It should be understood that this is only one interpretation of the claims and that the claims may have other proper and valid interpretations.

Referring to Fig. 7, the two pedicle screws are the claimed first and second biocompatible attachment devices. The posterior device 400 is the claimed flexible member. As described in the paper submitted October 16, 2008, in some embodiments, the flexible member flexes at the elastic connector connection, but also, the first and second components may be formed of a flexible material, such as a flexible polymer, for example.

Applicants believe that the confusion comes from not recognizing that the disclosed

pedicle screws meet the features of the claimed attachment devices. With the pedicle screws providing support for claim 42, there is no need for the four legs as discussed in the Office Action. Accordingly, Applicants submit that the claim particularly points out and distinctly claims the recited subject matter. Applicants respectfully request that the Examiner withdraw the rejection.

Compliance with 35 U.S.C. §103

The Office Action indicated that claims 42-48, 52-57, 60, and 61 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,238,396 to Lombardo in view of 2003/0220643 to Ferree. Applicants traverse the rejection.

Claim 42

Claim 42 is directed to a surgical implant for replacing functions of a facet joint between adjacent vertebrae. It includes first and second biocompatible attachment devices for attaching to pedicles and:

> a flexible member attached to the first and second biocompatible attachment devices configured in a manner to allow motion at the facet joint;
>
> wherein the first and second biocompatible attachment devices are positioned, and the flexible member is adapted, so that the surgical implant applies a distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance,
>
> wherein the flexible member includes:
>
> a first component comprising: an elongated body and a first joint element having a first opening;
>
> a second component comprising: an elongated body and a second joint element having a second opening wherein the second joint element is coupled with the first joint element;
>
> an elastic material disposed through both the first and second openings in a manner that dynamically secures the first and second

components together and elastically flexes in a manner that permits relative movement between the first and second components; and

a connector covering the first joint element and the second joint element, wherein the connector comprises the elastic material.

Emphasis added.

A. The combination fails to teach, suggest, or consider a surgical implant that applies a distracting force between the superior and inferior vertebrae

The Office Action fails to identify any portion of any applied reference that suggests a "flexible member is adapted, so that the surgical implant applies a distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance," as recited in claim 42. The device in Lombardo is a cross-connector that extends in a lateral direction across a vertebral posterior region. Because it does not even attach to superior and inferior vertebrae, but either connects to a single vertebra or between two rods, it cannot provide a distracting force between superior and inferior vertebrae as required by claim 42.

Ferree does not help. Ferree is relied on for a teaching of a protective cover. A protective cover on a cross-connector does not provide a distracting force between superior and inferior vertebrae as claimed because the cross-connector does not distract two vertebrae. Further, the other teachings in Ferree would not help because placing springs as in Ferree in a cross-connector as in Lombardo would still not provide any distracting force in the manner claimed.

The Response to Arguments section of the Office Action states that "Ferree shows an elastic material that surrounds a joint and provides flexibility to the two elongated portions—causing both a dynamic motion as well as a biasing force in securing the vertebrae." Office Action, p.6. But even if Ferree shows an elastic material, the combination still does not meet the features of claim 42. For example, even if Ferree disclosed an elastic sleeve that could be placed over the cross-connector of Lombardo, the resulting device would still be nothing more than a

cross-connector that does not apply a distracting force between the superior and inferior vertebrae. In fact, the cross-connector cannot apply a distracting force as claimed between two vertebrae when it is attached to only one vertebra or when it is laterally disposed along a single level to attach to two rigid, adjacent and parallel rods.

B. The combination fails to teach, suggest, or consider an elastic material disposed through both the first and second opening

The combination of references fails to suggest "an elastic material that flexes to impart flexibility to the flexible member, the elastic material being disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components," as recited in claim 42.

The Office Action relies upon Lombardo for a teaching of an elastic material disposed through both a first and second opening in first and second components. Although Lombardo discloses what appears to be a traditional screw, the Office Action states, "it would have been obvious to one having ordinary skill in the art at the time of the invention" to make the screw in Lombardo elastic because it is "within the general skill of a worker in the art to select a known material on the basis of its suitability of the intended use as a matter of obvious design choice." Office Action, pp.4-5. Figs. 3 and 6 from Lombardo are reproduced below.

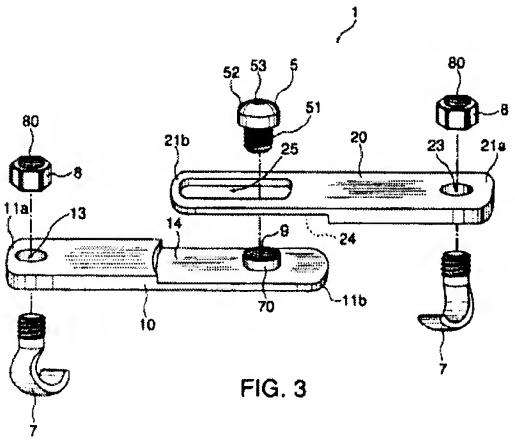

FIG. 3

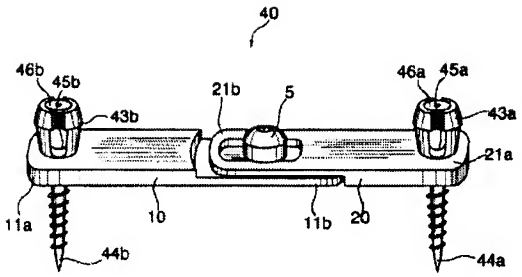

FIG. 6

Lombardo discloses a cross-connecting apparatus having a screw as a "tightening device 5." According to Lombardo, "[t]he tightening device 5 is positioned through the elongated aperture 25 of the second element 20 and within the central bore 9 of the first element 10 to secure the second element 20 onto the first element 10." Lombardo, col.9 ll.38-41.

But replacing the regular screw that secures the elements 10 and 20 together with an elastic screw that "elastically flexes in a manner that permits relative movement between the first and second components" would render the cross-connector unfit for its intended purpose. The cross-connector is intended to secure the rods together and eliminate any lateral movement of one rod relative to the other. So one skilled in the art would not replace the screw 5 with an elastic member intended to permit relative movement. A loose cross-connector might result in a loose rod. Thus, a cross-connector that elastically flexes would render the cross-connector unsuitable for its intended purpose of stiffening or strengthening the spine.

Accordingly, Applicants respectfully submit that the Office Action fails to establish a prima facie rejection and that claim 42 should be allowed as was indicated in the Office Action dated April 30, 2008.

Claim 60

Claim 60 is directed to a prosthetic device for replacing functions of a facet joint between adjacent vertebrae. It includes

> one or more flexible posterior devices configured to replace main functions of the facet joint, having a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible attachment device configured to attach to a second transverse process, and wherein the one or more flexible posterior devices includes a joint component positioned between the first and second biocompatible attachment devices,
>
> wherein the one or more flexible posterior devices comprises:
>
> a first elongated body; and
>
> a second elongated body,
>
> wherein the joint component includes:
>
> a first element associated with the first elongated body, the first element having a first opening, and
>
> a second element associated with the second elongated body, the second element having a second opening, wherein the second element is coupled with the first element by an elastic material disposed in both the first and second openings; and
>
> a connector covering the first element and the second element wherein the connector comprises the elastic material.

However, Applicants submit that the combination of references fails to include "one or more flexible posterior devices configured to replace main functions of the facet joint, having a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible attachment device configured to attach to a second transverse process." Instead, the Lombardo device is configured to attach to spinal rods or to pedicles. Ferree appears to discloses a device for connection to pedicles. Neither discloses "a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible attachment device configured to attach to a second transverse process," as recited in claim 60. Accordingly, the combination fails to teach or suggest all the features of claim 60.

Accordingly, Applicants respectfully submit that the Office Action fails to establish a prima facie rejection and that claim 60 should be allowed as was indicated in the Office Action dated April 30, 2008.

Claim 61

Claim 61 is like claim 42 in many respects but includes additional features. Those features are underlined in the reproduced claim below.

> A surgical implant for replacing functions of a facet joint between adjacent vertebrae, the surgical implant comprising:
>
> a first biocompatible attachment device for attaching to a first pedicle of a superior vertebrae;
>
> a second biocompatible attachment device for attaching to a second pedicle of an inferior vertebrae; and
>
> a flexible member attached to the first and second biocompatible attachment devices configured in a manner to allow motion at the facet joint;
>
> wherein the first and second biocompatible attachment devices are positioned, and the flexible member is adapted, so that the surgical implant applies a biasing distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance,
>
> wherein the flexible member includes:
>
> a first component comprising: an elongated body and a first joint element having a first opening;
>
> a second component comprising: an elongated body and a second joint element having a second opening wherein the second joint element is coupled with the first joint element;
>
> an elastic material that flexes to impart flexibility to the flexible member, the elastic material being disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components and the superior and inferior vertebrae; and
>
> a connector covering the first joint element and the second joint element, wherein the connector comprises the elastic material.

Applicants submit that claim 61 should be allowable for the reasons discussed above and because it recites additional patentable subject matter.

Dependent Claims

The dependent claims add additional features to respective independent claims and also are believed to be distinct from the art of record, for example for the same reasons discussed above with respect to their respective independent claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of these claims.

Conclusion

In view of the foregoing remarks, all of the claims currently pending in this application are in condition for allowance. A telephone interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application. To that end, the Examiner is invited to contact the undersigned at 972-739-6969.

The Office Action and other prior Office Actions contain characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Respectfully submitted,

Dustin T. Johnson
Registration No. 47,684

Dated: March 3, 2009

HAYNES AND BOONE, LLP
Customer No. 46333
Telephone: 972/739-6969
Facsimile: 214/651-5940
Client Matter No.: 31132.63
R221599

Certificate of Service

I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on March 3, 2009

Diane Sutton